

REMARKS

I. Claim Status

Claims 18 and 24-26, and 28-30 are presented for examination. Claim 27 has been canceled. Claim 18 has been amended to change the percent homology from 50% to 95%. Support for this amendment can be found, for example, on page 7, lines 30-33; page 9, line 37; and page 11, lines 3-5. The claim has also been amended to replace "engineered" with "evolved." Support for the amendment can be found, for example, on page 7, lines 31-33. Additionally, the term "homology" has been replaced with "identity." Support for the amendment can be found, for example, at page 9, line 26 to page 10, line 2. No new matter has been added.

II. Amendments to the Specification

The specification has been amended to remove reference to hyperlinks and to recite, instead, the name of the website. No new matter has been added.

III. Rejections under 35 USC 112, second paragraph

The Office Action rejects the claims as allegedly being indefinite because (1) step (b) allegedly lacks antecedent basis, (2) the claim recites percent homology instead of percent identity, and (3) the term "disease" is allegedly unclear. While Applicant disagrees with the rejection, the claims have been amended to even more clearly provide antecedent support in step (b), to recite percent identity rather than homology, and to clarify the meaning of "disease". Accordingly, Applicant respectfully requests reconsideration and withdrawal of the rejection.

IV. Rejections under 35 USC 112, first paragraph

A. Written Description

The claims continue to be rejected as allegedly failing to comply with the written description requirement under 35 USC 112, first paragraph. The rejection appears to be based on the alleged breadth of sequences having 50% homology with SEQ ID NO:2. While Applicant

disagrees with the rejection, the amendment to the claims should render the rejection moot. The claims have been amended to refer to sequences that have 95% identity with SEQ ID NO: 2, thereby reducing the breadth of the claimed subject matter and eliminating the basis on which the rejection was founded. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the rejection.

B. Enablement

The claims have further been rejected as allegedly lacking enablement under 35 USC 112, first paragraph. The Office Action appears to base the rejection on the fact that the application does not specifically disclose a particular polypeptide sequence with the requisite percent homology to SEQ ID NO: 2 that binds to a particular target.

Applicant initially notes that the burden is on the Examiner to provide sufficient reason as to why one skilled in the art could not make or use the claimed invention. *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993) (examiner must provide a reasonable explanation as to why the scope of protection provided by a claim is not adequately enabled by the disclosure). The reasons provided in the Office Action are insufficiently reasonable to support the rejection. The Office Action relies on the fact that Applicant has not recited a particular polypeptide sequence that binds to a particular target within the meaning of the claim to support the rejection, but lack of a working example is not enough because it does not raise reasonable doubt that the invention cannot be made and used as claimed without undue experimentation.

The Office Action also inappropriately discounts the prophetic examples provided throughout the application that provide detailed guidance as to how to make and use the invention. For example, the Office Action acknowledges that the application discloses methods for making PDZ hCASK variants that bind to BclA (page 10 of Office Action) but then discounts this disclosure because no particular sequence is provided. The Office Action also acknowledges that the application discloses a prophetic example of PDZ variants that bind to the light chain of botulinum toxin, but then inappropriately discounts the teachings since no actual sequence is provided. See Office Action pages 10-11. In determining whether an invention is enabled, the entire application should be considered, and all parts, including prophetic examples, should be

weighed in the determination. Accordingly, it was inappropriate to discount the plethora of examples provided in the application in assessing whether the claims were enabled.

In fact, the numerous examples in the application, coupled with the description, provide more than sufficient guidance to allow one skilled in the art to make and use the invention as claimed. For example, the application provides more than sufficient guidance as to how to prepare a variant of SEQ ID NO:2 through in vitro evolution techniques which are well known in the art. See Examples 7, 9, and 22. Further, the binding properties of the variant can be tested via routine binding assays, such as the ones provided for in Examples 10-13. Thus, the application provides more than ample guidance to make and use the invention without undue experimentation. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the rejection.

V. Rejection under 35 USC 102(e)

The claims are further rejected under 35 USC 102(e) as allegedly anticipated by Lu et al. (US 7312041). Applicants respectfully traverse the rejection because Lu et al. fails to teach each and every element of the claimed invention. First, Lu et al. fails to teach a PDZ domain having at least 95% identity with SEQ ID NO:2. Second, Lu et al. fails to teach an "evolved" PDZ domain. "Evolved" PDZ domains involve the preparation of a library of mutants which are then screened for particular properties. See page 10, lines 13-31 of the application. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.

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Applicant : Simon Delagrave
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Respectfully submitted,

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/Christine A. Goddard/

Christine A. Goddard, Ph.D.
Reg. No. 46,731

Fish & Richardson P.C.
225 Franklin Street
Boston, MA 02110
Telephone: (617) 542-5070
Facsimile: (877) 769-7945

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